K091441

synergetics™, inc.

Synergetics Adjustable Gas Pressured Infusion Tube Set
Section 5
510 (k) Summary
Submitted in accordance with the requirements of 21 CFR 807.92

OCT 30 2009

Applicant's Name and Address:	Synergetics, Inc. 3845 Corporate Centre Drive O'Fallon, MO 63368
Contact Person:	Gary Oliveros Synergetics, Inc. Quality Systems/ Regulatory Affairs Manager Phone: (636) 794-5107 Fax: (636) 794-5120 Email: goliveros@synergeticsusa.com
Date Prepared:	May 14, 2009
Device Trade Name:	Synergetics Sterile Adjustable Gas Pressured Infusion (AGPI) Tube Set
Common Name:	Air/ Fluid Tubing Set
Device Classification:	Class II
Class Name:	A review of the U.S. FDA's Product Code Classification Files at http://www.fda.gov/cdrh/prdcddes.html indicates a similar type device is not listed in 21 CFR Parts 862 – 892.
Product Code:	FRN
FDA Panel:	Ophthalmic
Predicate Device:	Peregrine Wet Set, K990518

Intended Use/ Device Description:

The Synergetics AGPI Tubing set is a PVC tubing set intended to deliver forced humidified air or fluid to the eye during ophthalmic surgery. The tubing set consists of a three channel IV spike, for insertion into a bottle of Balanced Salt Solution. The three way spike is designed to deliver air from an air supply unit through the solution; while the dual PVC tubing also administers humidified air (clear lumen) and saline (green stripe lumen); this dual PVC tubing has a three-way stopcock for proper connection.

Substantial Equivalence Basis:

This premarket notification contains descriptive information related to the intended use, operational characteristics and technological features that provide objective evidence that forms the basis of a substantial equivalence decision.

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Comparison of Technical Characteristics:

Predicate Device Comparison			
Criteria	**Predicate Device Peregrine Wet Set K990518**	**Predicate Device Alcon VGFI Tube Set K911808**	**Synergetics, Inc. AGPI Tube Set**
Indications for Use			
Pressured Air Delivered from	Bottle	Bottle/ system console	Bottle/ system console
Fluid Source	Bottle	Bottle	Bottle
Air System Required	Yes	Yes	Yes
3 way stopcock for air/ fluid selection	Yes	Yes	Yes
Extension tube for insertion into BSS Solution	Yes	Yes	Yes
Delivery line for air to stopcock	Yes	Yes	Yes
Delivery line for fluid to stopcock	Yes	Yes	Yes
Filtered Air Line for attachment to air system	Yes	Yes	Yes
Single Use	Yes	Yes	Yes
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Packaging (See Note 1)	Not known	Rigid PETG Tray	Tyvek/ Mylar Pouch
Note 1: Synergetics packaging configuration has been validated in accordance with ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices- Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems			

Quality Management System:

Synergetics is a BS EN 13485:2003 compliant company and is required to ensure our quality management system and design control practices fully comply with internal quality system standards and domestic regulations. Pursuant to our design control process, Synergetics has established a risk management process that ensures during the design validation phase, the safety and effectiveness of the device meets applicable input requirements and complies with applicable harmonized standards.

Risk Management:

Risk Management has been implemented and complies with ISO 14971, Medical Devices – Application of Risk Management to Medical Devices and GHTF/SGS/N15R8, Implementation of Risk Management Principles and Activities within a Quality Management System.

Sterilization Method:

Synergetics Adjustable Gas Pressured Infusion Tube Sets are sterilized in accordance with AAMI/ISO 11135 Medical Devices — Validation and routine control of ethylene oxide sterilization (EtO), Overkill Method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Synergetics, Inc.
c/o Mr. Gary Oliveros
Quality System/Regulatory Affairs Manager
3845 Corporate Centre Drive
O' Fallon, MO 63368

OCT 30 2009

Re: K091441
Trade/Device Name: Synergetics Adjustable Gas Pressurized Infusion (AGPI) Tube Set
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 9, 2009
Received: October 13, 2009

Dear Mr. Oliveros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

synergetics™ , inc.

Synergetics™ 510 (k) Submission
Synergetics Adjustable Gas Pressured Infusion (AGPI) Tube Set
Section 4 - Indications for Use

510(k) Number (if known):

Device Name: Synergetics Adjustable Gas Pressured Infusion (AGPI) Tube Set

Indications for Use: The Synergetics Sterile Adjustable Gas Pressured Infusion Tube Set is intended to deliver forced humidified air or fluid to the eye during ophthalmic surgery.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daryl Kaufman

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091441